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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,494	09/17/2001	James G. Castillo	3863.015	8042

7590 04/07/2003
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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 04/07/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/954,494

Applicant(s)

CASTILLO, JAMES G.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Request for the Continued examination(RCE) acknowledged

1. The request filed on 12/18/2002 for a RCE under 37 CFR 1.114 based on parent Application No. 09/700,102 is acceptable and a RCE has been established. An action on the RCE follows.

Status of Application

2. Acknowledgement is made of amendment filed 03/17/2003. It is noted that amendment after final filed on 10/15/02(see paper no. 7) has not been entered due to the reasons of the record(see advisory action, paper no.10). Thus, the claim 5 had not been canceled and still pending.

3. Claims 1-15 are pending and presented for the examination.

Double Patenting

4. Claims 5 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 15. As mentioned immediately above, claim 5 has not been canceled and still pending. Thus, the newly added claim 15 that recited the same limitation found in original claim 5 is substantially same. Appropriate cancellation request is required.

Claim 7 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 6. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites the limitation "the said volatile penetration enhancing agent" in claim 1. However, claim 1 does not recite the phrase "volatile penetration enhancing agent". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

8. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Inagi et al(US 6,429,228).

Inagi et al teach a local anesthetic for external use which is prepared by blending a homogeneous mixture of an anesthetic(e.g. lidocaine, prilocaine, 2-12%, column 2, lines 50-65); oleic acid, 1-7%(see column 3, lines 15-27); ethanol, isopropyl alcohol or a

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combination thereof (10-44%); and a pharmaceutically acceptable carrier, see table 1 and lines 10-25 at column 6 and abstract. It further teaches the process of making the said composition comprising the steps: (a) a mixture of a local anesthetic and oleic acid(the percutaneous absorption accelerator) is dissolved in a solution of ethanol and /or isopropyl alcohol; (b) the solution obtained is mixed with other carrier(s) by agitation and homonization to produce final product, see column 4, lines 60 to columns 5-6. Although Inagi et al do not use the term "lipophilic base", oleic acid is lipophilic base as defined in the claims and thus, the instant claims are met by the cited reference's teaching.

In respect to the limitations(i.e. evaporation, remainder less than 1%, or cool sensation) recited in claims 1, 6, or 10 respectively, the evaporation of volatile solvent(e.g. ethyl or isopropyl alcohol) is considered to be inherent feature because it would have been occurring naturally when the said solution is applied topically to the affected skin area. And the evaporation which will be carried out until less than 1wt% of the volatile solvent remains in the solution is also naturally occurring since the composition comprising same component is applied into the skin. Thus, Inagi et al teach all the critical elements required by the instant claims 1-7 and 10-15.

As to the claims 8 and 9, at column 5, table 1, group B, Inagi et al teach a gelling agent(e.g. sodium carboxymethylcellulose, 1%) and a beneficial additive(e.g. polyvinyl alcohol, sodium caprylate) included in the patented composition. It is well known to any skilled artisan about their functional role in manufacturing process as a thickening agent and emulsifier, respectively(see columns 4-5).

As to the limitation recited in claim 14(i.e. eutectic mixture of lidocaine and prilocaine), Inagi et al teaches the combination of prilocaine and lidocaine, see column 2, lines 53-54. They also suggest that the active agent can be obtained from the commercial source, see column 2, lines 48. It is well known in the art that the commercial product(e.g. EMLA®) is eutectic mixture of lidocaine and prilocaine. Thus one would envisaged the eutectic mixture of the said anesthetic combination of prilocaine and lidocaine utilized in the patent.

Thus, Inagi et al teach all the critical elements required by the instant claims and thus, the claimed subject matter is not patentably distinct over the prior art of the record. All the claims are anticipated and properly included in this rejection.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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A handwritten signature in black ink, appearing to read 'Vickie Kim', with a long, sweeping horizontal stroke extending to the right.

Vickie Kim,
Patent examiner

April 3, 2003

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